

UNITED STATES SURGICAL)	APPEAL OF DESIGNATION OF
CORPORATION and)	UNCONTROLLED HAZARDOUS
MALLINCKRODT LLC)	SUBSTANCE SITE AND ORDER
)	
ORRINGTON, PENOBSBOT COUNTY, MAINE)	FINDINGS OF FACT AND ORDER ON APPEAL
PROCEEDING UNDER 38 M.R.S.A. § 1365)	

Appendix A: Summary of Procedural History

1. First Procedural Order. In the First Procedural Order dated (January 16, 2009), the Presiding Officer ruled on Mallinckrodt's request for an administrative stay of the appeal pending the outcome of Mallinckrodt's litigation against the Commissioner in the U.S. District Court for the District of Maine.²² The Presiding Officer granted a stay of its proceedings only until the U.S. District Court ruled on the Commissioner's motion to dismiss Mallinckrodt's complaint.²³
2. Second Procedural Order. In the Second Procedural Order (dated May 29, 2009), the Presiding Officer lifted the administrative stay of the Board's proceedings in response to the U.S. District Court's granting of the Commissioner's motion to dismiss Mallinckrodt's complaint.²⁴ The Presiding Officer also found that the appeal proceeding is an adjudicatory proceeding under the Maine Administrative Procedure Act (Maine APA), and the order set the deadline for motions to intervene and objections.
3. Third Procedural Order. The Third Procedural Order (dated June 19, 2009) documented the Board's actions on the petitions to intervene, as described in Finding of Fact 3(A) above.
4. Fourth Procedural Order. The Fourth Procedural Order (dated July 2, 2009) documented the outcome of the prehearing conference held on June 26, 2009 and addressed two motions filed by Mallinckrodt: (a) Motion to Dismiss for Failure to Pursue Clean-up in Superior Court, and (b) Motion to Dismiss Compliance Order or, in the Alternative, Stay Proceeding for Failure to Adopt Rules of Practice. The Fourth Procedural Order denied both motions. In denying the first motion, the Presiding Officer ruled that "the Commissioner's authority to issue a clean-up order is not limited to emergencies or to situations in which a responsible party is currently engaged in handling hazardous substances at the site" and that "Title 38, § 1365 does not require the Commissioner to pursue clean-up of the site only by bringing a Superior Court action." As to the second motion, the Fourth Procedural Order ruled that "the absence of any agency rule of practice specific to this type of adjudicatory proceeding (an appeal under Title 38, § 1365) does not deprive the board of authority to hear and decide the appeal." The Presiding Officer also ruled that the Maine APA, 38 M.R.S.A. § 345-A and 1365, and ad hoc procedures established by the Presiding Officer (see Procedures Document discussed below) provide procedural guidance and ensure fairness to all parties.

²² Following issuance of the Commissioner's Order, Mallinckrodt filed suit in federal court seeking to enjoin enforcement of the Order and seeking a declaratory judgment that the Order is unlawful. *Mallinckrodt LLC v. Littell*, 616 F.Supp.2d 128, 130, 132 (D. Me. 2009).

²³ Prior to Mallinckrodt's request for stay of the appeal, the Commissioner agreed to stay any compliance deadline in the Order until the Board issued a final decision and that no penalties for noncompliance with deadlines in the Order would accrue during the stay period. Mallinckrodt and the Commissioner also agreed to stay the statutory deadlines for holding the hearing and issuing a decision.

²⁴ See *Mallinckrodt LLC*, 616 F.Supp.2d at 130, 150 (granting motion to dismiss based on abstention grounds).

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In addition, the Fourth Procedural Order addressed Mallinckrodt's request that it be permitted to introduce evidence regarding alleged political pressure on and bias of the Commissioner in issuing his Order. The Presiding Officer denied that request, ruling that "[t]he Board is the actual decision-maker in this proceeding; accordingly, questions related to alleged political pressure and bias in the Commissioner's decision-making process are not relevant to the Board's proceeding." The Presiding Officer explained: "In accordance with 38 M.R.S. § 1365(4), the Commissioner must establish the basis for the order and the naming of the person to whom the order is directed. Mallinckrodt has the opportunity to present evidence demonstrating that the order should be modified or rescinded. The Board will be making its decision based on the facts in the record which address the technical and scientific basis for the remedy. If the remedy ordered by the Commissioner is not supported by sufficient technical and scientific evidence to satisfy the Board that it is the appropriate remedy, questions related to political pressure and bias will not be germane to the discussion because the order will be modified or rescinded. Conversely, if the remedy offered has sufficient technical and scientific basis to demonstrate to the Board that it is the appropriate remedy, questions related to political pressure and bias will again not be germane because the remedy – however motivated – is justified by the technical and scientific evidence. For this reason, the issues to be addressed at the hearing will be limited to technical issues surrounding the remedy."

The Fourth Procedural Order also addressed participation of the parties in the hearing and conduct of the proceeding. The order attached and incorporated a final "Procedures Document" which was developed after input from all parties and which set forth procedures on the serving and filing of papers, public participation, conferences, presiding officer rulings, hearing location, pre-filed written testimony, exhibits, general conduct of the hearing, testimony and cross-examination, witnesses, offers of proof and continuances. Among other things, the Fourth Procedural Order set deadlines for the parties to submit lists of material factual issues and expert witnesses by issue area.

Mallinckrodt appealed the Fourth Procedural Order to the Board. After considering the appeal at the Board's regular July 16, 2009 meeting, the Board denied the appeal and affirmed the Fourth Procedural Order.

5. Fifth Procedural Order. The Fifth Procedural Order (dated July 29, 2009) documented the outcome of the prehearing conference held on July 24, 2009. In the order, the Presiding Officer reiterated certain clarifications she had made at the Board's regular July 16, 2009 meeting concerning the Fourth Procedural Order. Among these clarifications, the Presiding Officer stated that her ruling excluding presentation of evidence of alleged political pressure and bias does not prevent the parties from challenging a witness' credibility on cross-examination. The order provided that informal transcripts of regular Board meetings and prehearing conferences created by Mallinckrodt for its own use would not be included in the record of the appeal proceeding and prohibited citation to any such transcripts in submissions to the Board. The order set a deadline for the parties to submit written position statements on the legal standards applicable to the

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Board's consideration of the appeal, and the order set a deadline for the parties to confirm agreement on the media protection standards. In addition, among other things, the order addressed the role of the Board's consultant in the proceeding.

6. Sixth Procedural Order. In the Sixth Procedural Order (dated August 28, 2009), after considering written submissions by the parties, the Presiding Officer ruled that the Uncontrolled Hazardous Substance Sites Law is the governing law. As to the federal RCRA criteria, the Presiding Officer ruled that "[s]ince the RCRA criteria are not established in State law or rule, the Board is not required to make a finding on each of these criteria when reviewing the Commissioner's Order or any alternative remedy that may be put forward by Mallinckrodt." The Presiding Officer ruled that "the 11 RCRA criteria used by the parties in developing and evaluating alternative remedies are not legal standards to be met, but rather factors which may be considered by the Board when evaluating the remedy for the site and reaching its ultimate decision under the statute." Noting the potential usefulness of the RCRA criteria in evaluating alternative site remedies, the Presiding Officer ruled that "the parties may present relevant evidence on each of these factors."

As to the media protection standards set forth in Attachment 2 of the Commissioner's Order, the Presiding Officer noted that at the July 24, 2009 pre-hearing conference, Mallinckrodt and the Commissioner stated their agreement that the Numeric Media Protection Standards apply to remedy selection. The Presiding Officer noted that Mallinckrodt in a later memorandum stated it did not agree with the media protection standards, but it only specified one area of disagreement - regarding the narrative standards for soil. In the Sixth Procedural Order, the Presiding Officer set a deadline for Mallinckrodt to identify each media protection standard that it contests and the basis for the challenge.

Mallinckrodt appealed the Sixth Procedural Order to the Board. After considering the appeal at the Board's regular September 3, 2009 meeting, the Board denied the appeal and affirmed the Sixth Procedural Order.

7. Seventh Procedural Order. The Seventh Procedural Order (dated September 16, 2009) documented the outcome of the prehearing conference held on September 11, 2009. In the order, the Presiding Officer, among other things, addressed stipulations, the *de novo* standard of review, witness lists, submission of exhibits, demonstratives, pre-filed testimony and exhibits, and Board project orientation. As to the media protection standards, the Presiding Officer noted that Mallinckrodt confirmed that its only concern was with the narrative standard for soils and whether it could be interpreted to apply to the landfills. The Presiding Officer also requested that the parties submit their positions on the burden of proof and the record upon which the Board's decision will be based.
8. Eighth Procedural Order. In the Eighth Procedural Order (dated October 8, 2009, as revised October 15, 2009), after considering written submissions by the parties, the Presiding Officer made rulings concerning the burden of proof and the record upon which the Board's decision will be

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based. The Presiding Officer ruled that the Uncontrolled Sites Law addresses the burden of production and that at the hearing the “Commissioner will present testimony and evidence in support of his position first, after which Mallinckrodt will present testimony and evidence in support of its position.” The Presiding Officer also ruled that “each party bears the burden of persuasion with respect to the facts supporting the actions it wishes the Board to take.” Specifically, the Eighth Procedural Order states that:

[T]he Commissioner has the burden of persuading the Board that the statutory elements of the Uncontrolled Sites Law are met, namely that:

1. “Hazardous substances are or were handled or otherwise came to be located” at a specific location,
2. The hazardous substances at the location “may create a danger to the public health, to the safety of any person or to the environment,”
3. The ordered remedial action is “necessary to terminate or mitigate the danger or likelihood of danger,” and
4. The persons to whom the order is directed are “responsible parties.”

As to Mallinckrodt’s burden of persuasion, and based on Mallinckrodt’s position in the Notice of Appeal, the Presiding Officer ruled that “Mallinckrodt has the burden of persuading the Board that the Order should be revoked because the evidence does not support making the factual findings that underlie each of the statutory elements of the Uncontrolled Sites Law, or that the Order should be modified to make different factual findings regarding one or more of the statutory elements.”

The Presiding Officer ruled that the standard of proof for all findings of fact made by the Board is “preponderance of the evidence.” Regarding the record upon which the Board’s decision will be based, the Presiding Officer ruled that “the record before the Board will include all relevant evidence admitted during the course of the proceeding until the close of the record at the conclusion of the hearing, regardless of the date when the evidence was obtained.” The Eighth Procedural Order also addressed issues related to witness lists.

Mallinckrodt appealed the Eighth Procedural Order to the Board. After considering the appeal at the Board’s regular October 15, 2009 meeting, the Board denied the appeal and affirmed the Eighth Procedural Order.

9. Ninth Procedural Order. The Ninth Procedural Order (dated November 3, 2009) documented the outcome of the prehearing conference held on October 30, 2009. In the order, the Presiding Officer addressed the fact that pre-filed testimony of Mallinckrodt’s witnesses was not sworn, set deadlines for the parties to respond to motions to strike certain pre-filed testimony, and addressed witness issues concerning agency staff. In addition, the Presiding Officer referred to comments submitted by the Commissioner and Mallinckrodt on the draft presentation slides for the project

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orientation for the Board, and she set a deadline for comments on revised slides to be developed by Board staff. The project orientation for the Board was set for November 19, 2010.

10. Tenth Procedural Order. In the Tenth Procedural Order (dated November 10, 2009), after considering the motions to strike filed by the Commissioner and Mallinckrodt and the responses by the parties, the Presiding Officer ruled on the motions to strike as follows: (1) struck one sentence from Mallinckrodt witness Zeigler's pre-filed testimony; (2) struck the pre-filed testimony and accompanying exhibits of Mallinckrodt witness Thomas; (3) struck certain parts of the pre-filed testimony of Mallinckrodt witness DeVillars; (4) refused to strike certain pre-filed testimony of Mallinckrodt witnesses Vaillancourt, Bingham, and Chaffee; (5) refused to strike certain pre-filed testimony of Commissioner witnesses Fowler, Ostrowski, Lavallee, Stahler, Smith, and Ladner; (6) refused to strike certain pre-filed testimony of Commissioner witnesses Beane, Ladner, and Stahler, but ruled that parties must provide dates of sample data; (7) refused to strike the term "Mallinckrodt Site" from testimony presented on behalf of the Commissioner; (9) refused to strike certain pre-filed testimony of Commissioner Littell; and (10) refused to strike testimony of Maine People's Alliance witnesses Judd, Galland, Conmee, and Graham, but reallocated the testimony to the Orrington session of the hearing at which members of the public also testified.

Mallinckrodt appealed the Tenth Procedural Order's rulings as to witnesses Thomas and DeVillars to the Board. After considering the appeal at the Board's regular November 19, 2009 meeting, the Board denied the appeal and affirmed the Tenth Procedural Order.

11. Eleventh Procedural Order. The Eleventh Procedural Order (dated December 30, 2009) documented the outcome of the prehearing conference held on December 18, 2009. In the order, the Presiding Officer granted the Commissioner's motion to strike Mallinckrodt's request for DEP employee John James to appear as a rebuttal witness. The Presiding Officer addressed Mallinckrodt's motion to strike certain pre-filed rebuttal testimony of the Commissioner's witnesses as follows: (1) refused to strike reports of Phase I Report (from the Maine People's Alliance litigation in federal court) and related pre-filed testimony; (2) refused to strike certain statements by witnesses Littell and Ladner; (3) refused to strike testimony by witnesses that Mallinckrodt argued was unduly repetitious, among other things; (4) struck certain references in witnesses Hyland and Ladner's testimony to bankruptcy; (5) refused to strike certain references in witnesses Hyland and Littell testimony concerning the State's mercury policy and global greenhouse gas emissions; and (6) refused to strike testimony of witness Stahler regarding site redevelopment. In addition, the Presiding Officer addressed use of documents in cross-examination and demonstratives, witness issues, and hearing schedule and organization, among other items. The order also set deadlines for submittal of information on sequence of presentation of witnesses, composition of witness panels, and time required, as well as for submission of demonstratives.

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Mallinckrodt appealed the Eleventh Procedural Order's ruling allowing the Phase I Report and related testimony. After considering the appeal at the Board's regular January 7, 2010 meeting, the Board denied the appeal and affirmed the Eleventh Procedural Order.

12. Twelfth Procedural Order. In the Twelfth Procedural Order (dated January 6, 2010), the Presiding Officer ruled on Mallinckrodt's motion for legal ruling regarding the state acceptance criterion. The Presiding Officer referred to her earlier ruling on the role of the RCRA criteria in the proceeding and noted that as a practical matter the Board would determine in its decision what is acceptable to the State, but ruled that Mallinckrodt may cross-examine witness Ladner on her testimony and may argue in its post-hearing brief the weight the Board should give to the testimony on state acceptance of the remedy.
13. Thirteenth Procedural Order. The Thirteenth Procedural Order (dated January 13, 2010) documented the outcome of the prehearing conference held on January 12, 2010. In the order, the Presiding Officer addressed, among other items, hearing schedule, hearing logistics, post-hearing briefs, and deadlines concerning demonstrative exhibits.²⁵

²⁵ By email dated January 20, 2010, the Presiding Officer ruled that a number of Mallinckrodt's demonstratives would not be allowed for use at the hearing. By letter dated January 22, 2010, Mallinckrodt requested reconsideration of ten demonstratives. At a sidebar during the hearing, the Presiding Officer denied that request.